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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,834	04/24/2006	Bernd Stahl	0470-061191	2278

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,834	STAHL ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/07/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-30 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "modulating the immune system" in claims 17 is a phrase which renders the claim indefinite. More specifically, it is unclear how the administration of said composition can modulate the immune system since the modulation of the immune system requires both increase and decrease of immunostimulation and would involves opposite mechanism actions. That is, said composition cannot have the effect of increasing and decreasing immunostimulation simultaneously.

Claim 30 recites the phrase "n is an integer between 1 and 60, i.e. 2, 3, 4, 5, 6, ..., 59,

60". However, the claim is indefinite because it is unclear why 60 is included in the phrase "i.e. 2, 3, 4, 5, 6, ..., 59, 60" when n is between 1 and 60.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-26 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the instant particular oligosaccharide composition for treating a specific immune system related disorders in a mammal and particular or specific autoimmune disease, does not reasonably provide enablement for treating or preventing any immune system related disorders or any autoimmune diseases, encompassed by the claims by administering the said oligosaccharide composition.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of treating and/or preventing of immune system-related disorders including autoimmune disorders and other disorders recited in claim 18 herein.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating and/or preventing any of the numerous immune system-related disorder including autoimmune disorders and other disorders recited in claim 18 herein.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any immune system-related disorder including any autoimmune disorders, which are known to be involved various, many possible, different, separate and independent, even unknown pathology, etiologies, or symptoms. The method for the treatment of an autoimmune disease is not one but at least two distinct, separate, and independent methods. For example, as defined by Ninham et at. (WO 85/05031, PTO-892), the immune response in a human or animal subject can be suppression or enhancement (see page 1-2). Autoimmune diseases can be treated by artificial suppression (immunosuppression) or enhancement (immunopotentation), wherein these two treatments are involved in distinct and separate agents, processes and mechanisms, and most importantly which are in both opposite directions.

"To date, immunosuppressive drugs that have been developed to manipulate the immune response, are usually compounds of complex structure that have been discovered by accident. Further, their mode of action is often unknown or very unpredictable and administration of drugs can be accompanied by undersirable side-effects" (emphasis added). See page 2, in particular line 19-25.

The skilled artisan would view that the treating or preventing any autoimmune diseases, encompassing both suppression (immunosuppression) and enhancement (immunopotentation), by administering the VERY same oligosaccharide composition, as being **highly *unpredictable***. Therefore, the skilled artisan would view that the treatment of all immune system-related disorder including all autoimmune disorders herein, and including several diseases that are listed and that are encompassed in claim 18 herein by administering the same composition herein, is highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

In the instant case, **no** working examples are presented in the specification as filed showing how to treat a single autoimmune disease, i.e., no testing results provided.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any immune system-related disorder including all autoimmune disorders encompassed by the instant claims. As a result, necessitating one of skill to perform an exhaustive search and undue experimentation for the embodiments of treating any autoimmune diseases recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is

granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success. Similarly, claim 17 which is drawn to the modulation of the immune system in a mammal comprising the administration of the same said oligosaccharide, is also encompasses by this rejection since a modulation of the complete or entire immune system broadly includes or is directly related to treatment all or any of the system-related disorder set forth above, of which applicant is not enabled. In addition, it should be noted that a modulation of the immune system requires both increase and decrease of immunostimulation and would involves opposite mechanism actions. That is, said composition cannot have the effect of increasing and decreasing immunostimulation simultaneously.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. (US 2003/0022863 A1).

In claim 16, applicant claims a method for the treatment and/or prevention of an immune system-related disorder in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide and a neutral oligosaccharide, wherein: the acid oligosaccharide has a degree of polymerization between 1 and

250 and is prepared from pectin or alginate; and the neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooliogosaccharides and mixtures thereof. Claims 18-24 are drawn to the said method wherein the immune system-related disorder is a specific type including allergy types and wherein acid and neutral oligosaccharides are of specific types. Claims 25-26 are drawn to the said method wherein the composition is administered enterally and to humans of specific ages. Claim 17 is drawn to a method for enhancing the immune response and/or modulating the immune system in a mammal, comprising administering to the mammal the said composition comprising an acid oligosaccharide and a neutral oligosaccharide.

Stahl et al. disclose that the adhesions of pathogens, as well as of cell damaging substance on the surface of mammal cells which is an indispensable requisite for an infection (an immune system-related disorder) or a damage of the cell (e.g., inflammation of the skin cells an in an allergic reaction due to pathogens) can be prevented by their composition which comprises an acid oligosaccharide (oligogalactouronide) and a neutral oligosaccharide (galactooligosaccharides or inulin (an oligofructose), wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide (see page1, section [0002], page 2, section [0023] and page 5, example 8 sections [0054] to [0057]). Furthermore, Stahl et al. disclose that the pathogens include at least bacteria, viruses, fungi, monocellular or multicellular parasites, toxins and heavy-metal cations (see page1, section [0002]). This implies that infections such as bacterial, fungal, viral and parasitic infections (i.e., immune system related disorder) can be prevented or treated by the use

of their composition. In addition, Stahl et al. disclose that their composition can be used for treating infections of the gastrointestinal tract, the blood system, the respiratory passages, the urogenital tract, and the nasopharyngeal meatus, and for treating damages of the cells of the gastrointestinal tract, the blood system, the respiratory passages, the urogenital tract, and the nasopharyngeal meatus caused by toxins or heavy-metal cations (see claim 16).

The difference between applicant's claimed method and the method suggested by Stahl et al. is that Stahl et al.'s do not exemplify the administration of the their composition for preventing or treating an immune system-related disorder in a mammal. However Stahl et al. suggest that their composition could be administered to said mammal to prevent or treatan immune system-related disorder (pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic reaction due to pathogens).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Stahl et al. to administer Stahl et al.'s antiadhesive composition to prevent or treat an immune system-related disorder (such as pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic type reactions due to pathogens) in a mammal, since Sthal et al.'s suggest that their composition can be used to prevent or treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Stahl et al. to administer Stahl et al.'s antiadhesive composition to treat an immune system-related disorder (such as a pathogen infection) or a damage of the cell (which includes inflammation of the skin cells an characterized in an allergic type reactions due to pathogens) in a mammal, since a skilled artisan would reasonable expect to use the composition taught by Stahl et al. for the same said purpose. It should be noted that the use of specific routes of

administration such as enteral administration depends on factors such as the severity and location of the condition or disorder treated, the type, age and size of mammal. It should be noted that claim 17 which is drawn to a method for enhancing the immune response and/or modulating the immune system in a mammal comprising administering to the mammal the same said composition, is also encompassed by this rejection since a treatment of immune system-related disorder (such as pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic type reactions due to pathogens) as suggested by Stahl et al. with the said composition also implies the modulation of the immune system of the treated mammal.

Claim 27 is drawn to a food composition comprising specific % of lipid, protein, carbohydrate, acid oligosaccharide and neutral oligosaccharide, wherein said acid oligosaccharide comprises at least one terminal uronic acid unit, has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and said neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooligosaccharides and mixtures thereof. Claims 28 and 29 are drawn to the food composition of claim 27 having specific caloric density and viscosity. Claim 30 is drawn to a liquid composition comprising fat, carbohydrate, protein and specific amounts of soluble indigestible oligosaccharides (neutral oligosaccharides) and acid oligosaccharides.

Stahl et al. disclose a dietetic composition comprising an acid oligosaccharide (oligogalactouronide) and a neutral oligosaccharide (galactooligosaccharides or inulin (an oligofructose), wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide (see page1, section

[0002], page 2, section [0023] and page 5, example 8 sections [0054] to [0057]). Furthermore, Stahl et al. disclose that their composition is a dietetic (food) composition in that it contains usual food ingredients and food components, including vitamins and trace elements (see claim 13 and claim 1). In addition, Sthal et al.'s disclose that their composition has antiadhesive effect in that it can reduce and/or block the adhesion of pathogenic substances and organisms to eucaryontic cells, in particular mammal cells (see abstract).

The difference between applicant's composition and the composition of Stahl et al. is that Stahl et al.'s do not exemplify a specific food or dietetic composition which contains usual food ingredients and food components.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the food (dietetic) composition suggested by Stahl et al. and to include the usual food ingredients or components such as lipids, proteins and carbohydrates in different percentages in order to use it as an antiadhesive, since Sthal et al.'s disclose that their composition can be used to an antiadhesive to for reducing and/or blocking the adhesion of pathogenic substances and organisms to eucaryontic cells, in particular mammal cells.

One having ordinary skill in the art would have been motivated to prepare the food (dietetic) composition suggested by Stahl et al. and to include the usual food ingredients or components such as lipids, proteins and carbohydrates in different percentages in order to use it as an antiadhesive, since a skilled artisan would reasonable expect to use the composition taught by Stahl et al. for the same said purpose. It should be noted that the preparation of food compositions of specific caloric content and viscosity depends on factor such as type, age of the individuals to whom the composition is be administered. Also, it should be noted that claim 30

which is drawn to a liquid composition (a liquid food), is also encompassed by this rejection since applicant's composition contains the same oligosacchrides and since the preparation of a liquid form a composition such as the food composition suggested by Stahl et al. is common in the art and is well within the purview of a skilled artisan and depends on factors such as the type, age of the individuals to whom the composition is be administered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

4/4/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

March 30, 2007.